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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,224	09/14/2000	David Thomas Grose	1430-252	5556

7590 12/08/2004  
Nixon & Vanderhye  
8th Floor  
1100 North Glebe Road  
Arlington, VA 22201-4714

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/646,224

### Applicant(s)

GROSE ET AL.

### Examiner

Robert Landsman

### Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***1. Formal Matters***

- A. The Amendment dated 11/10/04 has been entered into the record.
- B. Claims 1-19 have been canceled. New claims 20-22 have been added. Therefore, claims 20-22 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

### ***2. Specification***

- A. The specification remains objected to since an Abstract could not be found in the Response dated 11/10/04.
- B. The objection to the specification has been withdrawn in view of Applicants' amendment to add the priority data in the first line.

### ***3. Claim Rejections - 35 USC § 101***

- A. No rejection of new claims 20-22 under 35 USC 101 will be made in view of Applicants' arguments that the present invention possesses utility. It is clear from Applicants' arguments that these proteins are only expressed on specific small-diameter sensory neurons in the DRG. The art appears to support this finding and that sodium channels on these cells are involved in pain. To use the proteins as a target for drug discovery, itself, is insufficient to demonstrate utility. However, it appears that these proteins can be used as a specific tissue marker. Therefore, the polynucleotide of the invention possesses utility since it can be used to produce the polypeptide which can then be used to produce the antibody which is then used as a tissue-specific marker for small diameter DRG neurons. If Applicants disagree with the Examiner's reasoning, they are urged to clarify the record.

### ***4. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement***

- A. No rejection of new claims 20-22 under 35 USC 112, first paragraph, will be made in view of the fact that Applicants' have demonstrated that the polynucleotide of the invention possesses utility.

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B. Claims 20-22 are rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 5-6 of the Office Action dated 5/10/04 regarding claims 8-10. Applicants argue that nucleic acids that have the sequences now claimed provide a channel that is operative without undue experimentation being necessary and that it would not require undue experimentation to make and determine (i.e. test) DNA sequences which meet the limitations of the claims.

These arguments have been considered, and is deemed persuasive in part. The part of the rejection concerning percent identity has been withdrawn in view of Applicants' amendment to the claim to recite no less than 80% identity. Regarding the remaining issues, the breadth of the claims remains excessive since Applicants have not provided a functional limitation. The hybridization steps are not only not complete, as discussed under 35 USC 112, second paragraph, but the range allows for an excessive number of polynucleotides to hybridize. A hybridization step of 35 degrees Celsius would allow for extreme "non-specific" binding of a large number of DNA molecules, especially in the absence of a high temperature (65 degree Celsius) wash step. In fact, a hybridization step of below 55-60 degrees, again, especially in the absence of a high temperature wash step is excessive.

Applicants have not provided any guidance or working examples other than providing tissue localization data for the two protein of the invention, the human protein not even being the full-length open reading frame. The Examiner respectfully reminds Applicants that the standard for enablement is "make and use" not "make and test." In the absence of sufficient guidance and working examples as to what the function would be of any protein encoded by any polynucleotide of the claims, undue experimentation would be required to practice the claimed invention. Without a functional limitation it is not predictable to the artisan what "determinations" to make on the DNA sequences in order to determine which sequences meet the limitations of the claims. In other words, it is not predictable for what the artisan is attempting to determine.

***5. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. Claims 20-22 are rejected under 35 USC 112, first paragraph, for the reasons already of record on page 7 of the Office Action dated 5/10/04 regarding claims 8-10. Applicants arguments are identical to those seen above under 35 USC 112, enablement. Therefore, these arguments are not deemed persuasive for the same reasons as above.

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**6. Claim Rejections - 35 USC § 112, second paragraph**

A. Claims 20-22 are rejected under 35 USC 112, second paragraph, for the reasons already of record on page 8 of the Office Action mailed 5/10/04 regarding claim 8. Applicants have not provided any arguments. It appears that Applicants have amended the claims to recite a hybridization temperature and a salt concentration. However, there are sufficient materials and steps omitted from the claims, including SSC concentration and a wash step.

**7. Claim Rejections - 35 USC § 102**

A. Claim 20 is rejected under 35 USC 102 for the reasons already of record on pages 8-9 of the Office Action mailed 5/10/04. **All cited art is included in this paragraph since the issue is identical.** Applicants argue

These arguments have been considered, but are not deemed persuasive. No functional limitation is recited in the claims. Therefore, all reference (prior art rejections) are being maintained since the hybridization conditions (e.g. 35 degrees Celsius) are low, there is no wash step, and there is sufficient overlap between the sequences of the prior art and the present sequences. Due to the high degree of overlap between any one of SEQ ID NO:3-17 and the prior art, it would be expected that the sequences of the prior art would hybridize even to a recombinant polynucleotide comprising SEQ ID NO:3-17.

**8. Note**

A. It is brought to Applicants' attention that any limitation recited in the claim which attempts to claim the polynucleotide encoding the full-length receptor, will raise written description issues under 35 USC 112, first paragraph since Applicants were not in possession of the full-length receptor, only SEQ ID NO:3-17.

**9. Conclusion**

A. No claim is allowable.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman  
Primary Examiner  
Art Unit 1647



ROBERT LANDSMAN  
PATENT EXAMINER